

Application Serial No. 09/765,151
Amendment dated September 2, 2005
Reply to Office Action dated June 3, 2005

REMARKS

Claims 1-19 and 21-29 are pending. Claims 1-9, 12-19, 21-23, and 25-29 are rejected. Claims 10, 11, and 24 are objected to, but the Examiner states would be allowable if rewritten in independent form to include the limitations of the base claim and any intervening claims. No claims are presently amended. As a result of the discussion below, it is believed that all claims are patentable and that this application is now in condition for allowance.

The Invention of the Present Application

The invention of the present application provides a composition and method for determining compliance with a medication regimen. This composition and method is rapid, simple, and inexpensive. In one embodiment, it includes an orally administrable composition in combination with at least one visual marker. This marker is present in a form and amount sufficient to cause a coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity of a patient. In various embodiments of the invention, by way of non-invasive observation of this coloration of the mucous or buccal membrane of the oral and/or pharyngeal cavity, one may obtain information regarding patient compliance with a medication regimen, such as whether the medication has been taken, the time elapsed since the medication was last taken, whether it is time for another dose of medication, etc. Thus, the present invention is very rapid, simple, and non-invasive as opposed to more invasive, tedious,

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and complicated monitoring methods of the prior art, such as the analysis of urine and stool samples, and injection of compositions.

Claim Rejections 35 U.S.C. § 102

The Examiner has rejected claims 1-7, 9, 15, 17-19, 22, 28, and 29 under 35 U.S.C. § 102(b) as being anticipated by Brilliant (U.S. Patent No. 3,309,274). In particular, the Examiner states that Brilliant discloses an orally administrable composition having a marker at a sufficient concentration to cause contact coloration of at least a portion of the mucous membrane of an oral cavity (citing column 1, lines 36-41, column 2, lines 23-72, column 3, lines 1-26, column 4, lines 9-75, and column 5, lines 15-26). The Examiner further states that with regard to the recitation "the half-life of said marker being comparable to the half-life of said composition," (which appears in the independent claims), the dye of Brilliant stains the oral cavity for a period after ingestion of the composition and thus has a half-life "comparable" to the half-life of the composition. The Examiner further states that the method steps in claims 1-7, 9, and 28 are inherently performed when the Brilliant composition is used to diagnose and treat oral conditions of a patient, such as skin lesions. Applicants respectfully disagree with the rejections over Brilliant.

Applicants first note that both independent claims 1 and 15 of the present application recite that the marker is in a form and amount to cause "a contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or

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pharyngeal cavity." Applicants assert that Brilliant does not teach or suggest any contact coloration of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity, as recited by independent claims 1 and 15. Applicants note that Brilliant is directed toward compositions including markers to stain disease-causing foreign matter in the oral cavity, for example, plaque, tartar, and the like (See column 1, lines 9-13). However, that staining does not occur on a mucous or buccal membrane. Rather, any staining in Brilliant occurs directly on the foreign matter (i.e., plaque, tartar, etc.) in the oral cavity (See at least column 2, lines 36-42 of Brilliant). If the product inherently stained the entire oral cavity, it would not perform its intended purpose identifying plaque, tartar, and the like. Brilliant does disclose (at column 2, lines 42-47) that when applied to certain skin lesions and the surrounding area, a fluorescent substance may stain the healthy skin tissue adjacent the lesions, while not staining the lesions themselves. However, the skin is exterior to the body and does not include the mucous or buccal membranes. Skin includes the cutaneous and subcutaneous tissues. The mucous and buccal membranes recited in the claims of the present application, on the other hand, are mucous-secreting membranes that line the oral and/or pharyngeal cavity. These membranes and the skin are wholly different substances. Again, there is no inherent disclosure of Applicants' invention.

Thus, Brilliant teaches staining foreign matter in the oral cavity, or staining skin. Brilliant does not teach a contact coloration of at least a portion of a mucous or

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buccal membrane, as recited in claims 1 and 15. In view of the above, Applicants assert that neither claim 1 nor claim 15 is anticipated by Brilliant. Since claims 1 and 15 are not anticipated, Applicants further assert that dependent claims 2-7, 9, 17-19, 22, 28, and 29 are also not anticipated by Brilliant. Thus, Applicants respectfully submit that the rejection of the claims as anticipated by Brilliant should be withdrawn.

The Examiner has rejected claims 1, 4, 9, 12-15, 17-19, 22, 23, and 25-29 under 35 U.S.C. § 102(b) as being anticipated by Block (U.S. Patent No. 3,723,613). In particular, the Examiner states that Block discloses an orally administrable composition with multiple markers (FDC Red No. 3 and FDC Green No. 3) that cause contact coloration of at least a portion of the mucous membrane of a patient (citing column 2, lines 17-24, column 3, lines 60-68; and column 4). With regard to the recitation "the half-life of said marker being comparable to the half-life of said composition," (which appears in the independent claims), the Examiner states that the dye of Block stains the oral cavity for a period after ingestion of the composition and thus has a half-life "comparable" to the half-life of the composition. Further, the Examiner states that the method steps of claims 1, 4, 9, 12-14, and 28 are inherently performed when the Block composition is used for diagnosis and control of plaque deposits (citing column 2, lines 38-55). Applicants respectfully disagree with the rejections over Block.

Again, Applicants note that both independent claims 1 and 15 of the present application recite that the marker is in a form and amount to cause "a contact

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coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity." Applicants assert that Block does not teach or suggest any contact coloration of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity. Applicants note that Block is directed toward a composition including markers to stain plaque. However, that staining does not occur on a mucous or buccal membrane. Rather, the staining in Block occurs directly on the plaque in the oral cavity (See at least column 1, lines 54-56, column 2, lines 26-32, and column 4, lines 25-29 of Block). Again, if Block inherently disclosed Applicants' invention, the Block invention would not perform its intended function, i.e., identifying plaque. Since no staining of the mucous or buccal membranes occurs by the composition of Block, Applicants assert that independent claims 1 and 15 are not anticipated by Block.

Since independent claims 1 and 15 are not anticipated by Block, Applicants further assert that dependent claims 4, 9, 12-14, 17-19, 22, 23, and 25-29 are also not anticipated by Block. In view of the above, Applicants respectfully assert that the rejection of claims as anticipated by Block should be withdrawn.

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected claims 8, 16, and 21 under 35 U.S.C. § 103(a) as obvious. In particular, the Examiner has rejected claims 8 and 21 as being unpatentable over Brilliant, and has rejected claim 16 as being unpatentable (1) over

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Block in view of Porter (U.S. Patent No. 4,643,894), and (2) over Brilliant in view of Porter. Applicants respectfully disagree.

Regarding the rejection of claims 8, 16, and 21 as obvious, Applicants note that each of those claims is a dependent claim from either claim 1 (from which claim 8 depends) or claim 15 (from which claims 16 and 21 depend). As discussed above, Brilliant (the primary reference used in the obviousness rejections of claims 8 and 21) does not teach the invention as claimed in independent claims 1 and 15. More specifically, Brilliant does not teach contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity. Further, Applications assert that neither does Brilliant suggest such contact coloration, such that it would have been obvious to one skilled in the art. In particular, as described above, Brilliant is directed to substances that can stain foreign matter in the oral cavity. The purpose of staining the foreign matter is to contrast it with the other areas of the oral cavity, so the foreign matter is easily visible (so that it can be treated). In such an instance, it would make no sense to also stain the mucous and buccal membranes, since that would detract from the contrast one is trying to achieve. Thus, claims 1 and 15 are nonobvious over Brilliant. As such, claims 8 and 21 are also nonobvious over Brilliant.

Regarding the rejection of claim 16, in order to establish a *prima facie* case of obviousness, the Examiner must show that the cited references, as combined,

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teach or suggest each of the elements of the claims. Claim 16 depends from independent claim 15, and thus incorporates limitations on that claim. At least for the reasons discussed above, neither Brilliant nor Block teaches or suggests each and every element of claim 15. More specifically, neither Brilliant nor Block teaches contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity. Further, it is submitted that Porter fails to teach the elements of claim 15 that are missing in Brilliant and Block. More specifically, Applicants assert that Porter simply teaches coatings that may be applied to tablets and/or pills. These coatings may include colors and may be supplied in order to impart a better taste to a particular tablet or pill. Porter, however, does not teach contact coloration of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity. Thus, regardless of whether one skilled in the art would be motivated to combine the teachings of Brilliant and Porter or Block and Porter, it is submitted that any combination of Brilliant, Block, and Porter does not show each and every element of claim 16, as that claim is dependent on claim 15.

In view of the above, Applicants respectfully assert that claims 8 and 21 are nonobvious over Brilliant, and claim 16 is nonobvious over Brilliant in view of Porter and is nonobvious over Block in view of Porter. Thus, Applicants submit that the rejection of claims 8, 16, and 21 as obvious under 35 U.S.C. § 103(a) should be withdrawn.

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Conclusion

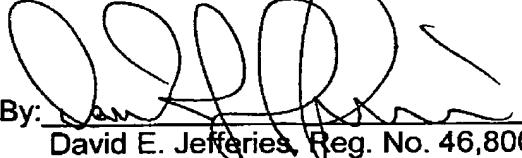
For the foregoing reasons, Applicants submit that all claims are patentable and a Notice of Allowance is respectfully requested.

No fee is believed due with this submission. However, if any fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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